



BIOMÉRIEUX

VIDAS[®] TB-IGRA

FULLY AUTOMATED TESTING SOLUTION



PIONEERING DIAGNOSTICS

Did you know?

LATENT TUBERCULOSIS, A HUGE RESERVOIR FOR A DEADLY DISEASE

Tuberculosis (TB): one of the top deadliest infectious disease worldwide

1/4 of people worldwide are infected with latent TB

Without treatment, **10-15%** of them are at risk to develop active TB disease



DIAGNOSIS OF LATENT TUBERCULOSIS INFECTION (LTBI)

A priority to:

- Prevent the development of TB disease
- Stop the spread of TB

CURRENT TB-IGRA TESTS ARE CUMBERSOME

SEVERAL STEPS & TUBES

NO GOLD STANDARD

HANDS-ON-TIME



WHAT IF YOU HAD ACCESS TO AN EASIER AND FULLY AUTOMATED TB-IGRA SOLUTION?

VIDAS® TB-IGRA

RELIABLE RESULTS FOR TB INFECTION

MORE CONFIDENCE IN IDENTIFYING INFECTED PEOPLE



HIGH SENSITIVITY
ON ACTIVE TB POPULATION*

VIDAS® TB-IGRA sensitivity

97.5% vs. **80.7%** for QFT®-Plus

The VIDAS® TB-IGRA assay gave

- **more true-positive results,**
- **fewer false-negative results,** than the comparative assay.



HIGH SPECIFICITY
ON POPULATION AT EXTREMELY LOW LEVEL OF TB INFECTION**

VIDAS® TB-IGRA specificity

97.6% vs. **95.2%** for QFT®-Plus



High capacity to identify active TB patients and non-TB-infected patients



STRONG AGREEMENT WITH COMPARABLE SOLUTION***
ON POPULATION WITH MIXED RISK OF TB INFECTION

92.1% VIDAS® Positive Percent Agreement (PPA)

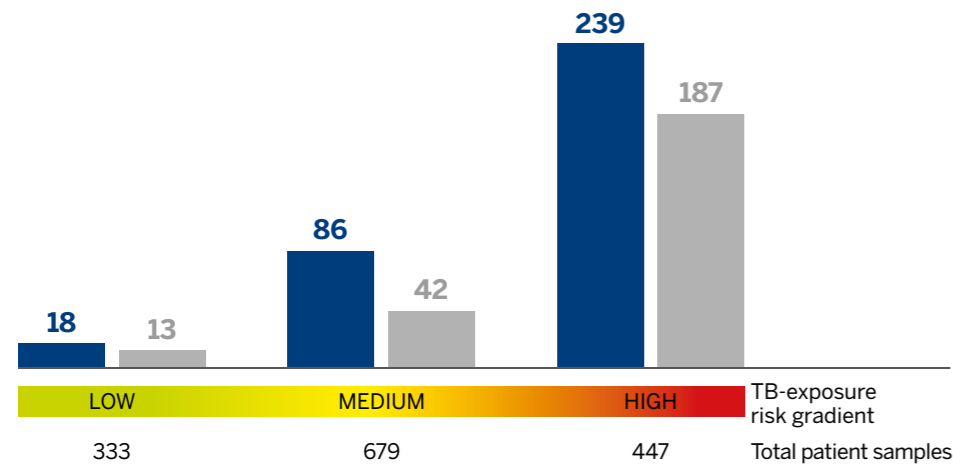
90.1% VIDAS® Negative Percent Agreement (NPA)

As there is no gold standard for the diagnosis of individuals with Latent TB Infection (LTBI), PPA and NPA with a comparative assay were determined.

* Evaluated on culture-confirmed active TB patients excluding indeterminate results
** Blood donors from a low endemic country considered at extremely low risk of TB infection
*** Compared to QuantiFERON®-TB Gold Plus test (QFT®-Plus)

FOR IMPROVED PATIENT MANAGEMENT

Positive results of the **VIDAS® TB-IGRA** (■) versus QFT®-Plus (■) in the Mixed Risk population



Detect more TB-infected individuals as risk becomes higher

Globally the rate of positive results was statistically higher ($\alpha=5\%$) for the VIDAS® TB-IGRA assay than for the QFT®-Plus assay (p-value < 0.0001).

As the TB-exposure risk increases, VIDAS® TB-IGRA detects more positive samples reflecting a stronger association with the expected likelihood of Latent TB Infection*.**

REDUCE CHALLENGES LINKED TO INDETERMINATE RESULTS

Analysis on indeterminate results

	VIDAS® TB-IGRA	QFT®-Plus
Indeterminate	0.1% (2/1660)	1.2% (20/1660)

The rate of indeterminate results was statistically lower ($\alpha=5\%$) for the VIDAS® TB-IGRA assay than for the QFT®-Plus assay (p-value = 0.0001).

VIDAS® TB-IGRA assay provides fewer indeterminate results*** : **high capacity to give valid, interpreted results to clinicians.**

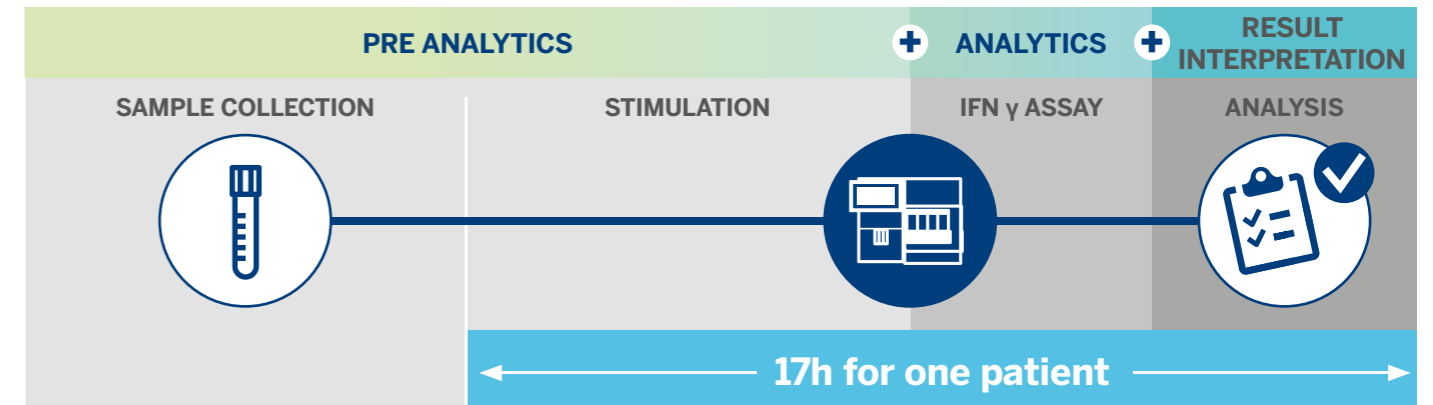
Reliable results for TB infection, greater ability to detect *Mycobacterium tuberculosis* infected persons

VIDAS® TB-IGRA

FULLY AUTOMATED SOLUTION

OPTIMIZE YOUR WORKFLOW

ALL STEPS MANAGED INSIDE THE VIDAS® 3 from a single whole blood tube



EASY TB-IGRA TESTING SOLUTION

- No multiple tubes to handle
- No sample preparation
- Simply load & go

GOOD ANALYTICAL PRECISION*

- The repeatability estimates (CV%) < 10.0%

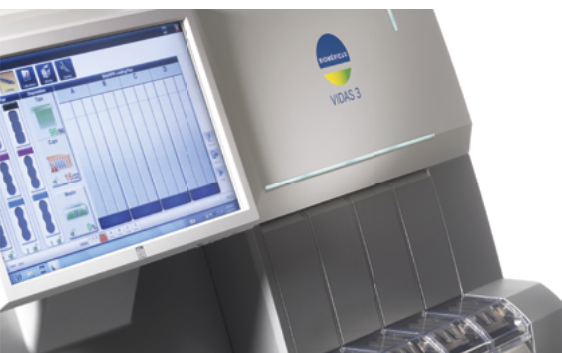
TAKE CONTROL OF YOUR TB-IGRA testing with VIDAS® 3

- **MINIMAL HANDS-ON-TIME**
Easy to use, simple process
- **QUICK TIME TO RESULT**
Results available in 1 day
- **COST-EFFECTIVE**
All materials included in the kit (calibration, controls)



SAVE TIME, AND TURNAROUND TIME


* Compared to currently available IGRA tests




AVAILABLE ON VIDAS® 3

BECAUSE IT MAKES SENSE ON VIDAS®

Easily manage TB testing within your activity



24/7
On-demand
automated
testing




100%
automated &
enhanced
traceability



Save time



**All-inclusive
kits**, limited
calibrations
and controls



Robust
MTBF > 700 days

	VIDAS® TB-IGRA	VIDAS® IFNg QC PANEL
Reference	423111	424069
Tests / kit	20 TB-IGRA tests 3 strips/SPR for 1 Patient test	N/A
Kit content	60 strips and 60 SPR S1, C1 Stimulation reagents	4 lyophilized vials (4x3 mL) 2 x IFNg QC1 x 3 mL 2 x IFNg QC2 x 3mL
Time to result	17h for 1 patient	43 min
Sample type	Whole blood (lithium heparin tube)	lyophilized recombinant human IFN-γ
Sample volume	300 µL x 3 (for the 3 strips)	150 µL
Calibration frequency	56 days	
Calibration protocol	43 minutes	

REFERENCES

- <https://www.who.int/teams/global-tuberculosis-programme/tb-reports>.
- <https://www.ecdc.europa.eu/en/tuberculosis>.
- VIDAS® TB-IGRA (Ref : 423111) Package insert 053331.
- Clinical Trials.